REMARKS

In the Claims:

Claims 22-26 are currently pending. Claims 22 and 25 are amended herein to clarify that the claimed antibodies are isolated. No new matter is added by this amendment.

In the Specification:

The disclosure was objected to as containing "embedded hyperlink and/or other form of browser-executable code." The foregoing amendment to the specification, which deleted all embedded hyperlinks, is believed to overcome the present objections. Further, any minor errors have been amended.

Accordingly, Applicants believe that all objections to the specification have been overcome and respectfully request they be withdrawn.

Rejections:

35 U.S.C. § 101

Claim 22 stands rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Examiner kindly notes that this ground of rejection may be overcome by amending claim 22 to recite "isolated" or "purified." Applicants have herein amended claims 22 and 25 to clarify that the claimed antibodies are isolated. Therefore, Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

Claims 22-26 stand rejected under 35 U.S.C. § 101 as allegedly not being supported by either a credible, specific and substantial utility or a well established utility. In particular, the Office action alleges that "the instant specification does not teach any significance or functional characteristics of the PRO361 polypeptide (SEQ ID NO:83) or antibody binding thereto."

Applicants respectfully disagree. In particular, at Example 34, found on page 141, Applicants disclose that the PRO361 polypeptide tested positive in the Mixed Lymphocyte Reaction (MLR) Assay. A positive reaction in the MLR assay illustrates

that PRO361 functions as an inhibitor of the proliferation of stimulated T-lymphocytes. At page 141, lines 8-9, the specification sets forth how PRO361 may be used, based on this function: "[c]ompounds which inhibit proliferation of lymphocytes are useful therapeutically where suppression of an immune response is beneficial." Based on this function of a PRO361 polypeptide, one of ordinary skill in the art would know that antibodies to PRO361 are useful for preventing suppression of an immune response.

Without acquiescing to the propriety of this rejection, but solely in the interest of expediting prosecution in this case, Applicants submit a declaration with supportive references from the art to show that the PRO361 polypeptides have immunosuppressive activity based on the positive results obtained in the MLR assay.

In particular, Applicants herein submit a declaration by Sherman Fong, Ph.D., of Genentech, Inc., an expert in the field of Immunology and listed co-inventor on the present application. Dr. Fong's declaration demonstrates that there are specific immune stimulant utilities for the compounds identified by an MLR assay. Specifically, Dr. Fong's declaration explains how the MLR reaction was performed in the instant application using peripheral blood mononuclear cells (PBMCs), which contain responder T-cells, and allogenic, pre-treated (irradiated) PBMCs, which predominantly contained dendritic cells. Further, Dr. Fong's declaration clearly states that:

> Some PRO polypeptides do the reverse, and give inhibition of T-cell proliferation in the MLR assay. It is my considered scientific opinion that a PRO polypeptide shown to inhibit T-cell proliferation in the MLR assay where the activity is observed as 80% or less of the control, as specified in the present application, would be expected to find practical utility when an inhibition of the immune response is desired, such as in autoimmune diseases.

Accordingly, the positive results obtained in this assay clearly establish the stated utility for the PRO361 polypeptides as immunosuppressors. Thus, the PRO361 polypeptides are useful where immunosuppression is desired, for example, in the treatment of graft rejections, autoimmune diseases, *etc.* Further, antibodies to the PRO361 polypeptides are useful when prevention of immunosuppression is desired. One of ordinary skill in the art will appreciate that antibodies to PRO361 polypeptides will bind such polypeptides and thereby block or decrease the immunosuppressive activity of PRO361

polypeptides. By the foregoing arguments and supportive evidence, Applicants have established that the MLR reaction is a generally recognized assay to assess immunoinhibitor as well as immunostimulatory activity.

Since the legal standard accepts the results of *in vitro* analyses for showing utility and because the results of the MLR assay described in Example 34 are "reasonably correlated" to the utility of the claimed antibodies, as discussed above, a valid case for utility has been made and would be considered credible by a person of ordinary skill in the art. Indeed, as set forth in MPEP § 2108 II (B)(1), if an applicant has asserted that the claimed invention is useful for any particular practical purpose, and the assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility should not be imposed. The logic underlying the asserted utility in the present case is not inconsistent with general knowledge in the art, and would be considered credible by a person skilled in the art. It is, of course, always possible that an invention fails on its way of development to a commercial product. Thus, despite recent advances in rational drug design, a large percentage of drug candidates fail, and never make it into a drug product. However, the USPTO is not the FDA, and the law does not require that a product (drug or diagnostic) be currently available to the public in order to satisfy the utility requirement.

Applicants respectfully submit that the specification provides sufficient disclosure to establish a specific, substantial, and credible utility for antibodies to the PRO361 polypeptide. Thus, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

35 U.S.C. § 112, first paragraph
Enablement

The Examiner contends that because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully disagree. As discussed above, the claimed antibody has the specific, substantial, and credible utility binding to a polypeptide that inhibits the

proliferation of stimulated T-lymphocytes as demonstrated in the MLR assay experiment discussed in Example 34 at page 141 of the application. Applicants respectfully request the Examiner reconsider and withdraw the rejection of claims 22-26 under 35 U.S.C. § 112 ¶1 for alleged inadequate disclosure on how to use the claimed invention.

SUMMARY

Applicants believe that currently pending Claims 22-26 are patentable and respectfully request allowance thereof. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite prosecution of this case.

Respectfully submitted,

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